



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

**Statement of the American Pharmacists Association
to the Food and Drug Administration**

**Open Public Meeting on Risk Evaluation and Mitigation Strategies (REMS)
for Certain Opioid Drugs**

Docket No. FDA-2009-N-0143

Wednesday, May 27, 2009

Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs

Good afternoon, I am Marcie Bough, a pharmacist and director of Federal Regulatory Affairs for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Thank you for the opportunity to present the views of the nation's pharmacists.

APhA recognizes that the Food and Drug Administration (FDA) regulates manufacturers and will hold them responsible for any Risk Evaluation and Mitigation Strategies (REMS). However, prescribers and pharmacists are the health care providers on the front-line of practice responsible for implementing REMS.

APhA supports FDA's efforts to assure appropriate use of long-acting and extended-release opioids. Unfortunately, many current risk management programs have presented challenges to practitioners. We must learn from the past so that any challenges with opioid REMS are addressed and intended outcomes are achieved.

Pharmacists are challenged by the growing number of FDA-mandated REMS. We are also concerned with the lack of standardization that creates new processes and systems for each new REMS, such as: communication tools and plans; REMS assessments; and elements to assure safe use, which may include requirements for prescriber and pharmacist training/education/certification, registries, restricted distribution, dispensing based on safe use conditions, monitoring, and implementation systems. These varied systems lead to administrative, logistical and workflow challenges.

While we recognize that each new drug product requiring a REMS will have different risks to address, REMS must be designed to ensure that workable and long-range goals are met. We believe FDA must require a common framework and set of requirements that make each program

more alike than different. We encourage FDA to work with the professions and other stakeholders to design in advance general concepts and principles that FDA could then require of manufacturers developing a REMS. America's pharmacists call for a long-term visionary solution that will stand the test of time and benefit, not burden, all involved.

If we design for the long-term, then the process for complying with a REMS can be streamlined. For example, documenting that a pharmacist understands a program and attests to his or her ability and commitment to meet the requirements could be a standard process for any REMS. Designing and implementing a REMS for certain opioids gives us an opportunity to create a standardized, system-based set of solutions for all REMS that, depending on the REMS, may vary by "module" and levels of intensity based on each product's risks for which the REMS is designed.

To better ensure success of an opioids REMS, APhA recommends the following, which are based on our members' feedback and front-line experiences with existing risk management programs:

1. Ensure that any solution is not overly burdensome on the healthcare system and does not prevent or delay patient access to appropriate pain therapy.
2. Ensure that REMS programs allow any willing pharmacist, physician, or other prescriber the opportunity to participate.
3. Ensure that a standardized, system-based approach is developed that can work for any drug, not just select opioids. The design of this system should be useful for future drugs and drug categories as well.
4. Ensure that a REMS system integrates seamlessly into practice workflow for physicians, other prescribers, and pharmacists, and integrates with all medical records and pharmacy management systems, including the utilization of electronic prescribing and electronic health records.
5. Ensure that the components of an opioid REMS are proven to be effective in mitigating the specific defined risks and are workable for patients, prescribers, pharmacists, manufacturers, wholesalers, and system vendors.
6. Clearly define the stakeholder accountable for implementing each REMS component.
7. Avoid potential unintended consequences of limiting health care provider participation, creating REMS "fatigue," or shifting risks, such as abuse and misuse, to other medications not included in a REMS.
8. Ensure that educational components are readily available to all physicians, other prescribers, and pharmacists who wish to participate. This education should not be overly burdensome.
9. Ensure that educational materials include:
 - A clearly communicated patient care plan;
 - A balance of risk and benefit information;
 - A brief therapeutic overview;
 - An explanation of why a REMS is in place;
 - The risks to be mitigated and tools intended to address those identified risks; and
 - REMS logistics – the procedures required to prescribe, process and dispense the medication to a patient.
10. Ensure that a REMS program serves as an adjunct to, not a replacement of prescriber/patient and pharmacist/patient dialogue about the benefits and risks of the medications and how to properly take, store, discontinue, and dispose of the medication.

11. Ensure that a feedback loop is designed to allow continuous improvement by determining why patient failures occur, rather than just documenting the failure.

Additionally, as REMS stakeholders, we need to fully understand the requirements and realities of what is being requested by FDA before adopting a solution. This means conducting sufficient real-life testing before launching so that once implemented, the solution is effective at mitigating the risks that are intended to be reduced. Given the scale of the proposed opioid REMS and the number of dispensing events that it will impact, we recommend that the Agency consider pilot testing the REMS so that effectiveness can be measured and glitches can be resolved prior to a nation-wide launch.

In the past, we worked with the Centers for Medicare and Medicaid Services (CMS) to help design an optimal prescription processing solution for Medicare Part D that worked for pharmacy and our patients. We are prepared to work equally as effectively with FDA and stakeholders to design and implement an optimal system and solution for opioid REMS. Only through a public-private partnership with FDA, manufacturers, pharmacists, physicians, other prescribers, and wholesalers at the table can a standardized and meaningful REMS system succeed.

Finally, based on FDA's request to pharmacy stakeholder participants at the May 5, 2009 meeting, APhA is continuing to gather additional feedback from pharmacists on lessons learned from existing risk management programs. We will provide additional information and answers to the questions listed in the Federal Register meeting notice as part of our final written comments.

We strongly encourage FDA to develop a collaborative approach that utilizes the expertise of all stakeholders responsible for implementing REMS. Thank you for your consideration. We look forward to working with you on this important issue.

###

Marcie A. Bough, PharmD
Director, Federal Regulatory Affairs
American Pharmacists Association
2215 Constitution Avenue, NW
Washington, DC 20037-2985
202-429-7538
mbough@aphanet.org